

DETERMINATION OF NEED PROGRAM
INFORMATIONAL BULLETIN ON INNOVATIVE SERVICES AND
NEW TECHNOLOGY

The Determination of Need Regulations 105 CMR 100.020 define "Substantial Change in Services" for acute care hospitals as "the addition, or expansion of, or conversion to a new technology or innovative services..." For purposes of this requirement, the Department has adopted the following principles in defining innovative services and new technology:

Innovative service: 1) treatment modality or diagnostic procedure which requires additional professional training and skills and specific institutional characteristics to provide the service; or 2) a service determined by the Department to have significant implications for the cost, quality, availability, appropriateness, or accessibility of health care to the public.

New Technology: 1) Medical or surgical equipment used primarily for diagnostic and treatment purposes which requires pre-market approval (PAM) from the U.S. Food and Drug Administration; 2) medical or surgical equipment which has been authorized for physician use by appropriate professional societies, but which is determined by the Department not to be in general use in the Commonwealth for patient care by physicians qualified to operate such equipment; or 3) modification of medical or surgical equipment which requires a different kind of technology for that operation from that in use when the equipment received PAM.

Innovative services and new technology include the following:

INNOVATIVE SERVICES

Air Ambulance
Extracorporeal Membrane Oxygenation (ECMO)
Invasive Cardiac Services (Open Heart Surgery
and Left Ventricular Assist Devices)

Neonatal Intensive Care Units
Organ Transplantation
Megavoltage Radiation Therapy

NEW TECHNOLOGY

Positron Emission Tomography (PET)
Extracorporeal Shock Wave Lithotripter (for gallstones)

Magnetic Resonance Imager (MRI)